

**SUMMARY OF THE
ON-SITE ASSESSMENT COMMITTEE MEETING
OCTOBER 3, 2001**

The On-Site Assessment Committee of the National Environmental Laboratory Accreditation Conference (NELAC) met by teleconference on Wednesday, October 3, 2001, at 1:00 p.m., Eastern Daylight Time (EDT). The meeting was led by Chairperson Mr. Alfredo Sotomayor, of the Wisconsin Department of Natural Resources. A list of action items is given in Attachment A. A list of participants is given in Attachment B. *The purpose of the meeting was to address items of importance identified in the committee's previously distributed meeting agenda.*

INTRODUCTION

Mr. Sotomayor called the meeting to order and reviewed the Agenda.

TOPICS OF DISCUSSION

Status of Action Items

- Dr. Frederic Siegelman, Chairperson of the Quality Systems Committee, responded to the proposed language prepared by On-Site Assessment Committee to Section 5.5.3.1. The Quality Systems committee may not have sufficient time to review and comment on our draft in time to discuss at NELAC-7i.
- The committee completed reviewing Chapter 3 to determine its consistency with other chapters. The committee did not find any major inconsistencies between Chapter 3 and Chapters 2 and 5, but noted the following:
 - Chapter 4 – 4.4.1.8 recognizes failure to pass an on-site assessment as a reason for
 - (1) denying an initial application. However, Chapter 3 is not entirely explicit about what constitutes “passing” an assessment.
 - (2) Chapter 6 – At NELAC 6 an editorial change was made to distinguish between assessments of laboratories and of accrediting authorities. Assessors would assess laboratories, and evaluators would evaluate accrediting authorities. However, in making the editorial changes in Chapter 6, the term “assessment” and “assessor” were replaced globally with “evaluation” and “evaluator” in sections pertaining to laboratories. Mr. Sotomayor will contact Mr. Louis Johnson, Chair of the Accrediting Authority Committee about this matter.

- (3) Chapter 1 – The glossary will need to redefine the term “assessor” to designate the inspector of a laboratory and add the term “evaluator” to designate the inspector of an accrediting authority. Similar distinctions need to be made or included for the terms “evaluation” and “assessment”.
- The Accrediting Authorities Workgroup had not met to make final the draft of the document describing the elements that would be part of an on-site assessment. The committee felt that it could be beneficial to have a joint teleconference with the Accrediting Authorities Workgroup or to have a draft of the Workgroup’s proposal for discussion at the interim meeting. Mr. Sotomayor will contact Dr. Kenneth Jackson on these matters.

Agenda for NELAC-7i OSA Session

The Committee is scheduled to have a full day session on Thursday, December 6.

After some deliberation the On-Site Assessment Committee agreed that the following topics could be included in its session as part of the NELAC-7i Conference Agenda:

- Draft Appendix C, including changes suggested at NELAC 6
- Discussion of the Accrediting Authorities Workgroup proposal for On-Site SOPs, if available
- Draft of Appendix D, including changes suggested at NELAC 6 and a clarification of the section on “evaluation phases”
- Comments to Chapter 3
- Comments on the existing Chapter 5 Checklists
- Effects of the changes to Chapter 5 related to PBMS on on-site assessments
- NELAC laboratory assessments, a listening session where participants could share their experiences or voice their concerns.

Appendix C and Appendix D

Within the context of the work the committee has invested in Appendices C and D, there was some discussion as to whether it might be prudent to establish mechanisms by which the NELAC Board of Directors could guide the priorities and topics of the projects committees undertake. A participant thought this could be accomplished if the Board would engage in some strategic planning. Establishing such a procedure would ensure that committees would channel their resources into productive areas and would

reduce duplication of efforts. Another member suggested that the Conference itself could pass resolutions directing specific committees to work on specific topics. Some committee members felt that resolutions directing work in the abstract might not result in meaningful products.

The committee considered the current situation regarding SOPs for conducting on-site assessments. A committee member stated that the on-site laboratory evaluations seemed to be inconsistent because there is not a clear requirement that all accrediting authorities have SOPs for conducting on-site assessments. The conference is still debating whether to require AAs to maintain these SOPs. If there were a directive to maintain SOPs for conducting on-site assessments, the committee and the conference then could concentrate on the contents of these SOPs.

To illustrate the necessity for requiring SOPs for conducting assessments, a committee member shared some anecdotal information about a laboratory whose assessment was “suspended” or terminated. When the laboratory requested the reasons for the interruption, the laboratory was told that this was in “accordance” with the NELAC standards. When the NELAC standards did not reference the reason for the assessment termination, the AA told the laboratory that the reasons for the termination were in the AA’s procedures. The committee member suggested that this type of inconsistency would be minimized if the elements of SOPs for performing assessments were part of the NELAC standards.

Although some committee members felt that the current version of Appendix C was too “procedural”, members agreed that it was within the realm of Appendix C to require addressing conditions leading to terminating an assessment. Since it is understood that these SOPs cannot be confidential, a committee member cautioned that on-site assessment SOPs should not require divulging specific procedures that would be used to evaluate allegations of improper laboratory practices. Another member suggested that the SOPs need only address enforcement procedures generally, especially in cases where laboratory assessors are also enforcement or compliance agents for AAs.

Discussing Appendix D, the committee agrees that this is closer to its purpose statement: *“The purpose of Appendix D is to specify elements of test methods that assessors must evaluate to determine whether a laboratory is executing methods properly, in accordance with documented procedures or with applicable regulations, whichever the case may be.”*

The committee discussed whether to combine Appendices C and D since both deal with the mechanics of performing assessments. The committee decided to keep the appendices separate for discussion at the interim meeting. The committee will decide later how to best present the information for inclusion in the NELAC Standards, depending on what feedback it receives before the next annual meeting.

Next Steps

Mr. Sotomayor agreed to make changes to Appendix D consistent with past discussions and comments received at NELAC 6. He will ask the committee to quickly review the changes to Appendix D and will submit drafts of Appendix C and D to Ms. Jeanne Hankins.

ADJOURNMENT

They're being no further business, the meeting was adjourned.

NEXT MEETING

The next teleconference will be held Wednesday, October 17, 2001, from 1:00-3:00 p.m., EDT.

ACTION ITEMS
ON-SITE ASSESSMENT COMMITTEE MEETING
OCTOBER 3, 2001

| Item No. | Action | Date to be Completed |
|-----------------|--|-----------------------------|
| 1 | Mr. Sotomayor will make changes to Appendix D, send them to the committee for review and submit them to Ms.Hankins. | 10/06/01 |
| 2 | Mr. Sotomayor will forward the latest version of Appendix C to Ms. Hankins. | 10/06/01 |
| 3 | The committee will continue to discuss Appendix C and consider any comments received from the AA Workgroup <i>10/3: Awaiting comments from AA Workgroup</i> | Ongoing |
| 4 | Mr. Sotomayor will contact Mr. Louis Johnson regarding wording in Chapter 6 on laboratory assessments. | 10/31/01 |
| 5. | Mr. Sotomayor will contact Dr. Jackson to discuss possible joint teleconference or joint discussion session at the interim meeting. | 10/31/01 |
| 6 | The committee will finalize the agenda for its session at the interim meeting. | 10/31/01 |
| 7 | The committee will meet by teleconference. | 10/17/01 |

**PARTICIPANTS
ON-SITE ASSESSMENT COMMITTEE MEETING
OCTOBER 3, 2001**

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